REMARKS

Claims 5, 6 and 27 have been amended to incorporate the subject matter of the density range of a solid dosage form produced by the present process. Support for the amended language of claims 5, 6 and 27 may be found in lines 9 -13 on page 9 of the specification. Claims 1 and 11 has been amended to clarify the claim language. Claims 12 – 26 have been cancelled. The Applicant reserves the right to continue the subject matter of claims 12 -26 in a corresponding continuing application.

Claims 13-26 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-15 of U.S. Pat. No. 6,083,531 ('531) in view of Schultz et al. (US Pat. No. 6,194,395 ('395) or Pharmaceutical Dosage Forms and Drug Delivery Systems. (Ansel et al.). The Applicant has cancelled these claims, therefore, the rejection on these grounds is now moot. The Applicant respectfully requests that the Examiner withdraw the rejection the judicially created doctrine of obviousness-type double patenting based on these grounds.

Claims 1-11 and 27 are rejected under 35 U.S.C. 103(a) over Humbert-Droz et al. WO 97/38679 (WO679). The Examiner states that although WO 679 is silent as to the teaching of compacting the prepared powder or granulate, that no unexpected or unusual results are seen in the particular step since the process disclosed in WO679 produces a fast disintegrating tablet.

Applicants disagree with the Examiner and respectfully request that the rejection under 35 U.S.C. 103(a) over Humbert-Droz et al. WO 97/38679 (WO 679) be withdrawn. The reference WO 679 does disclose and claim a process which produces a fast disintegrating solid dosage form. However, the process claimed in WO 679 is wholly different than the Applicant's present invention. The WO 679 reference teaches a process that requires that all of the ingredients of the intended solid dosage form are dissolved or suspended in a solvent first, and the solution or suspension is placed in a mold and the solvent of the solution or suspension is then evaporated to produce a solid mass which takes the shape of the mold. In contrast, the Applicant's process employs the use of a *compacted* powder or granulate which is placed in a mold in combination with a solvent, which solvent, is evaporated under reduced pressure to produce a solid dosage form. Clearly, the Applicant's process employs a step which uses a compacted mass and the reference WO 679 does not. In the third paragraph on page 5 of WO 679, it also states that the dosage form of the referenced invention "is manufactured without applying any compression force." This is a required aspect of the particular invention of WO 679 as stated in the same paragraph in the reference. Compression would violate the intent of the process to make a low density solid dosage form disclosed in WO 679. Thus the WO 679 reference teaches away from the Applicant's process which must employ a compressed or

compacted powder or granulate. In contrast to the invention of WO 679, the Applicant's process, uses a solvent, which, as it is evaporated, passes through the compacted powder or granulate in the mold, to produce a solid dosage form which is of much lower density than that of typical solid dosage forms such as tablets. The evaporative effect of the solvent through the powder or granulate allows it to be highly porous as the solvent bubbles or passes through the compacted mass. This aspect is not suggested nor allowed by the invention disclosed and claimed in WO 679.

Based on the foregoing the Applicant respectfully requests that the rejection under 35 U.S.C. 103(a) over Humbert-Droz et al. WO 97/38679 be withdrawn. There is not only no suggestion or motivation to employ the Applicant's claimed process but, in fact, the WO 679 reference teaches away from the Applicant's use of a compacted powder or granulate. In addition, the Applicant employs a compacted powder or granulate in combination with a solvent which solvent is evaporated through the compacted mass to enable the compacted mass to become a solid dosage form which is porous and thus of low density and capable of being rapidly dissolved.

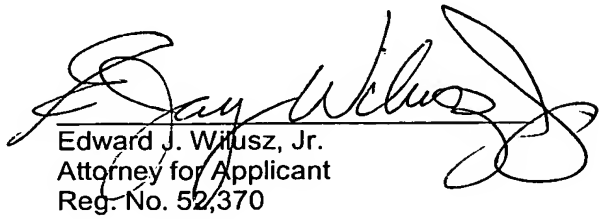
Claims 13-26 were rejected under 35 U.S.C. 103(a) over WO679 in view of Schultz et al. US 6,194,395. The Applicants have cancelled these claims from the present application and thus respectfully submit that the rejection on these grounds be withdrawn.

The Examiner has also rejected claims 13-26 under 35 U.S.C. 103(a) over WO679 in view of Pharmaceutical Dosage Forms and Drug Delivery Systems (Ansel et al.). The Applicants have cancelled these claims from the present application and thus respectfully submit that the rejection on these grounds be withdrawn.

Based on the foregoing the Applicant submits that the Application is now in condition for allowance and respectfully request early notice that effect. If it will advance prosecution of the Application, the Examiner is urged to contact the Applicant's undersigned counsel at the telephone number shown below.

No additional fees other than the fee for petition for extension are believed due, however, the Commissioner is hereby authorized to charge any fees which may be required in connection with this response, or credit any overpayment to Deposit Account No. 19-0134.

Respectfully submitted,



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